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10/575,931	04/14/2006	Hiroyuki Ebinuma	289708USOX PCT	7044
22850	7590	10/02/2008		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER COOK, LISA V	
			ART UNIT	PAPER NUMBER
			1641	
			NOTIFICATION DATE	DELIVERY MODE
			10/02/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/575,931

Applicant(s)

EBINUMA ET AL.

Examiner

LISA V. COOK

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-48 is/are pending in the application.
- 4a) Of the above claim(s) 38-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-37 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 20-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 4/14/06 7/7/06 3/28/07
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Inventor's Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 20-37 and 48) with traverse in the reply filed on 6/20/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The Restriction Requirement is still deemed proper and is therefore made **FINAL**.

2. Currently, claims 20-48 are subject to Restriction and Election Requirement. Claims 38-47 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as claims drawn to a non-elected invention. Claims 20-37 and 48 are currently under examination.

Priority

3. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). The first line of the specification should be updated to include PCT/JP04/15260 filed 10/15/04 which claims priority to Japan 2003-354930 filed 10/15/2003. Appropriate correction required.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the Examiner on form PTO-892 or Applicant on form PTO-1449 has cited the references they have not been considered.
5. The Information Disclosure Statement filed 4/14/06 has been considered as to the merits prior to first Acton.
6. The Information Disclosure Statement filed 7/7/06 has been considered as to the merits prior to first Acton.
7. The Information Disclosure Statements filed 3/28/07 has been considered as to the merits prior to first Acton.

Specification

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The disclosure is objected to because of the following informalities:

I. The use of the trademarks has been noted in this application. (.i.e. TWEEN on pages 23 and 24). All trademarks in the disclosure should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

II. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to **a single paragraph** on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

9. In the instant application, the abstract filed 4/14/06 is more than one paragraph. Appropriate correction is required.

Claim Objections

10. Claims 21, 22, 23, 29, 30, 32, 33, 34, 35, and 48 are objected to because of the following informalities: The claims utilize several acronyms. They include HMW-Ad, LMW-Ad, MMW-Ad, PAGE, HRP, ELISA, etc. Although the terms may have art-recognized meanings, it is not clear if applicant intends to claim any prior art definition of the abbreviations. The terms should be defined in their first instance. The initial explanation will convey intended meaning of subsequent abbreviations in the claims. Please define.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 21 is vague and indefinite because, although the claim is directed to the quantification of HMW-Ad (claim 21 step b), the method does not appear to recite that HMW-Ad is apart of the digested multimers in step a. It is suggested that the claims clearly identify that the analyte of interest will be present in the sample tested in order to obviate this rejection.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

I. Claims 20 and 31 are rejected under 35 U.S.C. 102(a) as being anticipated by Waki et al. (The Journal of Biological Chemistry, Vol.278, No..41, 10/10/03, pages 40352-40363).

Waki et al. teach SDS-PAGE (2-15%) methods of analyzing human and mouse adiponectin multimers. The multimers included HMW, MMW, and LMW. An anti-globular domain antibody was employed to measure adiponectin (at least one antibody that binds to adiponectin). For example, see abstract and figure 1. This terminology appears to be the same compositions referred to in the specification and claims as ULMW-Ad, LMW-Ad, MMW-Ad, and HMW-Ad. See disclosure page 5.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

II. Claims 21-30 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waki et al. (The Journal of Biological Chemistry, Vol.278, No..41, 10/10/03, pages 40352-40363) in view of Kondo et al. (Diabetes, July 2002, Vol.51, No.7, pages 2325-2328).

Please see Waki et al. (The Journal of Biological Chemistry, Vol.278, No..41, 10/10/03, pages 40352-40363) as set forth above.

Waki et al. differ from the instant invention in not specifically teaching protease treatment of the sample.

However, Kondo et al. teach procedures which detect adiponectin in type 2 diabetes. A protease generated globular segment was found to enhance fatty acid oxidation in muscles, thereby modulating lipid and glucose metabolism. Plasma adiponectin levels are inversely correlated with the severity of insulin resistance.

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With respect to claims 25 and 26, it is noted that Kondo et al. disclosure the use of a protease in their procedure. The type of protease use is deemed mere optimization of the procedure set forth in the prior art absent evidence to the contrary.

It would have been prima facie obvious to one of ordinary skill in that art to utilize the adiponectin protease digestion exemplified by Kondo et al. in the adiponectin detection method of Waki et al. (The Journal of Biological Chemistry, Vol.278, No..41, 10/10/03, pages 40352-40363) because Kondo et al. (Diabetes, July 2002, Vol.51, No.7, pages 2325-2328) taught that A protease generated globular segment was found to enhance fatty acid oxidation in muscles, thereby modulating lipid and glucose metabolism. Plasma adiponectin levels are inversely correlated with the severity of insulin resistance. Adiponectin is also taught to be indicative of various other diseases including type II diabetes. See page 40352.

One of ordinary skill in the art would have been motivated to protease digest adiponectin in order to monitor diseases associated with lipid and glucose metabolism (type 2 diabetes). See page 40352.

III. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waki et al. (The Journal of Biological Chemistry, Vol.278, No..41, 10/10/03, pages 40352-40363) in view of Kondo et al. (Diabetes, July 2002, Vol.51, No.7, pages 2325-2328) and further in view of Foster et al. (U.S. Patent #4,444,879).

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Please see Waki et al. (The Journal of Biological Chemistry, Vol.278, No..41, 10/10/03, pages 40352-40363) in view of Kondo et al. (Diabetes, July 2002, Vol.51, No.7, pages 2325-2328) as set forth above.

Although Waki et al. (The Journal of Biological Chemistry, Vol.278, No..41, 10/10/03, pages 40352-40363) in view of Kondo et al. (Diabetes, July 2002, Vol.51, No.7, pages 2325-2328) teach the reagents required by the claims; they do not specifically teach the reagents in kit configurations. In other words, the reference fails to teach the reagents as a kit. However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example. In their patent kits including the reactant reagents, a microplate, positive controls, negative controls, standards, and instructions are taught. The reagents are compartmentalized or packaged separately for utility. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay reagents as taught by Waki et al. (The Journal of Biological Chemistry, Vol.278, No..41, 10/10/03, pages 40352-40363) in view of Kondo et al. (Diabetes, July 2002, Vol.51, No.7, pages 2325-2328) and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit.

Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay. Kits are also economically beneficial in reagent distribution.

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14. For reasons aforementioned, no claims are allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached on (571) 272-0806.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit: 1641
Remsen 3
571-272-0816
9/28/08

/Lisa V. Cook/
Examiner, Art Unit 1641